

APR - 1 2010

## 510(k) Summary

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Date Prepared: March 1, 2010

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**Device Name** Proprietary name: Elecsys Troponin I CalCheck 5  
Common name: Troponin I CalCheck 5  
Classification name: Single (specified) analyte controls (assayed and unassayed)

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**Predicate device** The Elecsys Troponin I CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys HCG+ $\beta$  CalCheck 5 (K092168).

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**Device Description** The Elecsys Troponin I CalCheck 5 is a lyophilized product consisting of recombinant human cardiac Troponin I in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

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**Intended use** The Elecsys Troponin I CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Troponin I reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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## 510(k) Summary, Continued

**Comparison Table** The table below compares Elecsys Troponin I CalCheck 5 with the predicate device, Elecsys HCG+ $\beta$  Calcheck 5 (K092168).

Characteristic	Elecsys HCG+ $\beta$ CalCheck 5 (K092168)	Elecsys Troponin I CalCheck 5
Intended Use	The Elecsys HCG+ $\beta$ CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG+ $\beta$ reagent on the indicated Elecsys and <b>cobas e</b> immunoassay analyzers.	The Elecsys Troponin I CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Troponin I reagent on the indicated Elecsys and <b>cobas e</b> immunoassay analyzers.
Levels	Five	Same
Format	Lyophilized	Same
Matrix	Human serum matrix	Same
Handling instructions	Reconstitute the contents of each vial with exactly 1.0 mL distilled or deionized water.  Allow the bottle to stand closed for 15 minutes. Mix gently by inversion to ensure homogeneity.	Same
Stability	<u>Unopened:</u> • Store at 2-8°C until expiration date  <u>Reconstituted:</u> • 20 – 25°C : 4 hrs	Same

**Performance Characteristics** The Elecsys Troponin I CalCheck 5 was evaluated for value assignment and stability.

**Conclusion** The data demonstrate that the performance of the Elecsys Troponin I CalCheck 5 is substantially equivalent to that of the predicate device, Elecsys HCG+ $\beta$  CalCheck 5 (K092168).



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Roche Diagnostics  
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Regulatory Affairs Consultant  
Roche Professional Diagnostics  
9115 Hague Road, P.O. Box 50410  
Indianapolis, IN 46250-0416, USA

**APR 01 2010**

Re: k100594  
Trade/Device Name: Elecsys Troponin I CalCheck 5  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (Assayed and Unassayed)  
Regulatory Class: Class I, reserved  
Product Code: JJX  
Dated: March 1, 2010  
Received: March 2, 2010

Dear Ms. Baumann

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

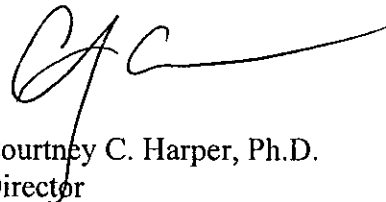
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K100594

Device Name: Elecsys Troponin I CalCheck 5

Indication For Use:

The Elecsys Troponin I CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Troponin I reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use   X    
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use         
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K100594